



IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Edward Bilenski et al. Group Art Unit: 3731
Serial No.: 10/822,243 Examiner: N/A
Filed: April 9, 2004
For: "SINGLE-USE, SELF-CONTAINED TWIST RESISTANT
SURGICAL KNIFE"
Matter No.: 0075-2

Bedminster, NJ 07921
August 19, 2004

Commissioner for Patents
Alexandria, VA 22313-1450

Sir:

PETITION TO MAKE SPECIAL FOR NEW APPLICATION
UNDER M.P.E.P. § 708.02 (VIII)

Applicant hereby petitions to make special this new application. The application has not yet been examined by the United States Patent and Trademark Office (the "Office").

Applicant submits that all of the claims in this case are directed to a single invention. As a prerequisite to the grant of special status, if the Office determines that all claims presented are not obviously directed to a single invention, then applicant will make an election, without traverse.

A pre-examination search of the subject matter encompassed by the above-identified application has been made by a professional searcher. The pre-examination search was conducted in the United States Patent and Trademark Office. The field of search covered Class 30, subclasses 162, and 335; Class 606, subclasses 167, 170, 181, and 182. Additionally, a computer database search was conducted on the USPTO systems EAST and WEST. Examiners Hwei Siu Payer in Class 30 (Art Unit 3724) and Julian Woo in Class 606 (Art Unit 3731) were consulted in confirming the field of search. The references developed by the pre-examination search were cited in applicants' Information Disclosure Statement dated June 22, 2004. A statement pertaining to the

In re application of: Edward Bilenski et al.
Serial No.: 10/822,243
Filed: April 9, 2004
For: SINGLE-USE, SELF-CONTAINED TWIST RESISTANT
SURGICAL KNIFE
Matter No.: 0075-2

Page 2 of 2

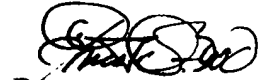
pre-examination search listing the references deemed most closely related to the subject matter encompassed by the claims is submitted herewith.

Applicant also submits herewith a detailed discussion of the references, which discussion particularly points out how the claimed subject matter is distinguishable over the references.

Enclosed herewith is a check in the amount of \$130, to cover the fee for this Petition. In the event that any additional fee is deemed to be required by 37 C.F.R. 1.17(h), it is requested that applicants be contacted at (908) 201-0220 and provided an opportunity to effect payment thereof.

A duplicate of this petition is attached.

Respectfully submitted,
Edward Bilenski et al.



By _____
Ernest D. Buff
(Their Attorney)
Reg. No. 25,833
(908) 201-0220



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Edward Bilenski et al. Group Art Unit: 3731
Serial No.: 10/822,243 Examiner: N/A
Filed: April 9, 2004
For: **"SINGLE-USE, SELF-CONTAINED TWIST RESISTANT
SURGICAL KNIFE"**
Matter No.: 0075-2

Bedminster, NJ 07921
August 19, 2004

Commissioner for Patents
Alexandria, VA 22313-1450

Sir:

STATEMENT PERTAINING TO PRE-EXAMINATION SEARCH
IN ACCORDANCE WITH MPEP § 708.02(VIII)

In accordance with MPEP § 708.02 (VIII), applicants, by and through their attorney, hereby submit that a pre-examination search was made for the above-identified application. The search was conducted by applicants' agents at the United States Patent and Trademark Office. The field of search covered Class 30, subclasses 162, and 335; Class 606, subclasses 167, 170, 181, and 182. Additionally, a computer database search was conducted on the USPTO systems EAST and WEST. Examiners Hwei Siu Payer in Class 30 (Art Unit 3724) and Julian Woo in Class 606 (Art Unit 3731) were consulted in confirming the field of search. The references developed by the pre-examination search were cited in applicants' Information Disclosure Statement dated June 22, 2004.

In re application of: Edward Bilenski et al.
Serial No.: 10/822,243
Filed: April 9, 2004
For: SINGLE-USE, SELF-CONTAINED TWIST RESISTANT
SURGICAL KNIFE
Matter No.: 0075-2

Page 2 of 2

The search identified the following U. S. Patents:

UNITED STATES PATENTS

Ref. #	Patent No.	Inventor(s)
1	845,792	L.E. Jenkins
2	1,424,221	G. Trumpeter
3	2,512,237	E.E. Mravik
4	3,906,626	Riuli
5	5,330,492	Haugen
6	5,417,704	Wonderley
7	5,556,409	Haining
8	5,741,288	Rife
9	5,779,724	Werner
10	5,908,432	Pan
11	6,022,364	Flumene et al.

Each of the foregoing references have been identified and discussed in the Detailed

Discussion of the References Submitted in Compliance with MPEP § 708.02(VIII).

Respectfully submitted,
Edward Bilenski et al.

By 

Ernest D. Buff
(Their Attorney)
Reg. No. 25,833
(908) 201-0220



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Edward Bilenski et al. Group Art Unit: 3731
Serial No.: 10/822,243 Examiner: N/A
Filed: April 9, 2004
For: **"SINGLE-USE, SELF-CONTAINED TWIST RESISTANT
SURGICAL KNIFE"**
Matter No.: 0075-2

Bedminster, NJ 07921
August 19, 2004

Commissioner for Patents
Alexandria, VA 22313-1450

Sir:

**DETAILED DISCUSSION OF THE REFERENCES SUBMITTED
WITH THE INFORMATION DISCLOSURE STATEMENT
IN COMPLIANCE WITH MPEP § 708.02 (VIII)**

In accordance with MPEP § 708.02(VIII), applicants hereby submit a detailed discussion of references applicable to the above-identified application. Each of these references was listed in the Information Disclosure Statement filed with the United States Patent and Trademark Office on June 22, 2004, in connection with the above-identified application.

1. U. S. Patent No. 845,792 to Jenkins

US Patent 845,792 to Jenkins (hereinafter the "'792 patent") discloses a knife having a hollow handle and a retractile blade that extends out of the handle and into position by a spring mechanism released by a laterally sliding pin. The knife also has foldable hand-guards that are extended when the blade is projected from the handle. Retraction and protraction of the '792 patent's knife blade is achieved by operation of the spring which is located within the handle. This

In re application of: Edward Bilenski et al.
Serial No.: 10/822,243
Filed: April 9, 2004
For: SINGLE-USE, SELF-CONTAINED TWIST RESISTANT
SURGICAL KNIFE
Docket No.: 0075-2

spring extends through the handle and comes into contact with a block located at the end of the inner most portion of the blade. Sufficient strength bears on the block by the spring so that the blade is thrust out of the handle when the spring is released.

Significantly, the '792 patent discloses a knife that is predisposed for repeated, continuous use through retraction and protraction of the knife blade. The knife blade of the '792 patents is extended outward or projected when the spring is released by a laterally moving pin. The patent does not disclose shaft support and lateral stabilization of the knife blade. Furthermore, the knife blade must be physically pushed back into the handle when retraction of the blade is desired, such as when the knife is not being used. The retraction of the knife blade disclosed in the '792 patent is not achieved by a twist mechanism, nor is the retraction permanent, but is merely temporary until the knife is subsequently used. In contrast, the invention called for by applicants' claims 1 – 6 discloses a single use, self-contained twist resistant surgical knife and process of making the same.

Unlike the knife disclosed in the '792 patent, the surgical knife called for by applicants' claims 1 – 6 is a single-use, twist resistant surgical knife that is sterile and ready for use, defined as the 'in-use' mode. Applicants' claims 1 – 6 recite a surgical knife having a blade initially in the extended or protracted position so that the blade does not have to be protracted from the containment. When the surgeon finishes using the applicants' claimed surgical knife a knurled ring member is turned by a turning means. The invention recited by applicants' claims 1 – 6 has a turning means that operates via a single twist, or "one-twist" turn, triggering retraction of the knife blade into the containment. Multiple use of the applicants' claimed surgical knife is thereby

In re application of: Edward Bilenski et al.
Serial No.: 10/822,243
Filed: April 9, 2004
For: SINGLE-USE, SELF-CONTAINED TWIST RESISTANT
SURGICAL KNIFE
Docket No.: 0075-2

prevented as the blade is not retractable from the containment from which it is housed upon retraction.

The applicants' claims 1 – 6 define a “one- twist” blade retraction feature that virtually eliminates and prevents accidental injury to the surgeon or hospital staff when the knife is retracted. The twist feature delineated by applicants' claims 1 – 6 is achieved by a turning member which turns a knurled member that releases the central spring tension, thereby retracting the knife into the containment permanently after single use. The permanent retraction of the applicants' claimed surgical knife into the containment prevents others from being injured when handling the medical waste containing the used surgical knife. During use of the applicants' single-use surgery knife recited by claims 1 – 6, twisting and jostling of the blade is prevented as the blade has stabilization means to prevent twisting and lateral stabilization means for support.

These structural differences patentably distinguish the invention called for by applicants' claims 1 – 6 from the '792 patent disclosure.

2. U. S. Patent No. 1,424,221 to Trumpeter

US Patent 1,424,221 to Trumpeter (hereinafter the “221 patent”) discloses an ice pick that is retractable into the handle against a spring. A handle is provided having an elongated socket that resiliently houses a pick point capable of being rigidly locked to the handle in either a projected or retracted position. Locking of the pick point is achieved by way of a tubular nut that secures the pick point.

In re application of: Edward Bilenski et al.
Serial No.: 10/822,243
Filed: April 9, 2004
For: SINGLE-USE, SELF-CONTAINED TWIST RESISTANT
SURGICAL KNIFE
Docket No.: 0075-2

The '221 patent discloses a retractable and lockable ice pick that is supported by a spring within the handle. The disclosed ice pick does not have both lateral stabilization means and longitudinal stabilization means by way of at least two shaft support bushings and slot faces. In contrast, the surgical knife disclosed by applicants' claims 1 – 6 comprises a containment means, stabilization means, retraction means, locking means, and a turning means. Specifically, the applicants' claims 1 – 6 recite both a lateral stabilization means, by way of at least two shaft support bushings, for supporting a shaft carrying the blade and a stabilization means, having at least a pair of slot faces, for preventing twisting of the blade. The locking means recited by applicants' claims 1 – 6 comprises a rectangular lug and rectangular opening in a knurled ring member so that the knife blade is initially locked in the extended or in 'in-use' position. After a single use of applicants' surgical knife defined by claims 1 – 6 the knurled ring member is turned with "one twist" and the blade is retract permanently into the containment casing.

In view of these structural and procedural differences, the invention delineated by claims 1 – 6 patentably differentiates the '221 patent disclosure.

3. U. S. Patent No. 2,512,237 to Mravik

US Patent 2,512,237 to Mravik (hereinafter the "237 patent") discloses a pocket implement. The blade of the implement is retracted within a flattened cylindrical sheath enclosure, thereby permitting the implement to be safely carried in a pocket or handbag. The blade is exposed by pushing the sheath into the handle against a spring, and is held in place by a catching mechanism.

In re application of: Edward Bilenski et al.
Serial No.: 10/822,243
Filed: April 9, 2004
For: SINGLE-USE, SELF-CONTAINED TWIST RESISTANT
SURGICAL KNIFE
Docket No.: 0075-2

The '237 patent discloses a knife wherein the blade is guarded by a flattened, cylindrical, movable sheath. Such a knife is appointed to be carried in a pocket or handbag without injury, and wherein the blade portion may be a knife or a nail file. The blade is protracted and retracted by way of a spring in a continuous, repeated manner.

On the other hand, the surgical knife required by applicants' claims 1 – 6 is a single-use, twist resistant surgical knife that is sterile and projected prior to use. When the surgical knife defined by applicants' claims 1 – 6 is used, the blade is permanently retracted into the containment member through "one-twist" of a turning member that sequentially turns a knurling member. After use the applicants' claimed surgical knife is readily discarded in a safe and sanitary manner, preventing injury and possible contamination to the surgeon, other hospital personnel, and the patient.

Specifically, the surgical knife required by applicants' claims 1 – 6 comprises a containment means, stabilization means, retraction means, locking means, and a turning means. The stabilization means recited by applicants' claims 1 – 6 provide both lateral and longitudinal stabilization to the knife blade by preventing the blade from shifting and twisting. The surgical knife delineated by claims 1 – 6 has a locking means that comprises a rectangular lug misaligned to a rectangular opening in a knurled ring member, for locking the knife blade when the blade is projected in the 'in-use' position. The applicants' claims 1 – 6 further require a turning means for turning the knurled ring member to release the rectangular lug and retract the knife blade permanently into the containment. These features are clearly absent from the '237 patent disclosure.

In re application of: Edward Bilenski et al.
Serial No.: 10/822,243
Filed: April 9, 2004
For: SINGLE-USE, SELF-CONTAINED TWIST RESISTANT
SURGICAL KNIFE
Docket No.: 0075-2

In view of these structural and procedural differences, claims 1 – 6 patentably differentiate the '237 patent disclosure.

4. U. S. Patent No. 3,906,626 to Riuli

US Patent 3,906,626 to Riuli (hereinafter the “'626 patent”) discloses a unitary disposable surgical scalpel. The scalpel is supplied with the blade exposed. After use it is pushed into a sheath where it is permanently locked, and the scalpel is disposed.

The '626 patent discloses a unitary scalpel in which the blade is retracted into a sheath and permanently locked for safe disposal. Once locked, the sheath cannot be removed without completely destroying the sheath. The surgeon essentially holds the sheath during use of the knife. The sheath is moved so as to expose the blade, and is again moved and permanently locks to conceal the blade. The '626 patent does not provide a “one-twist” retraction locking mechanism. Furthermore, the '626 patent does not provide both lateral and longitudinal stabilization to prevent blade slippage and twisting. In contrast, the surgical scalpel of the '626 patent may be vulnerable to twisting between the sheath and the retractable blade, preventing precise incisions of the surgical blade.

On the other hand, the surgical knife called for by applicants' claims 1 – 6 has both a lateral stabilization means supporting a shaft carrying the blade and a stabilization means preventing twisting of the blade. The locking means required by applicants' claims 1 – 6 comprises a rectangular lug and rectangular opening in a knurled ring member so that the knife blade is initially locked in the extended or in 'in-use' position. After a single use of applicants' surgical knife set forth by claims 1 – 6 the knurled ring member is turned with “one twist” and the blade is retract permanently into the

In re application of: Edward Bilenski et al.
Serial No.: 10/822,243
Filed: April 9, 2004
For: SINGLE-USE, SELF-CONTAINED TWIST RESISTANT
SURGICAL KNIFE
Docket No.: 0075-2

containment casing through a spring mechanism. This instant retraction feature defined by applicants' claims 1 – 6 is much safer than mechanisms that mechanically push a knife into a sheath, such as is utilized by the '626 patent, since the latter mechanism increases chances that the blade might slip, cutting the surgeon's hands.

In view of these structural and procedural differences, the invention delineated by claims 1 – 6 patentably differentiates the '626 patent disclosure.

5. U. S. Patent No. 5,330,492 to Haugen

US Patent 5,330,492 to Haugen (hereinafter the "492 patent") discloses a safety scalpel attached to the forward end of a handle. A spring biased retractable sheath is positioned within the handle. Blade retraction is actuated by depressing a single button, which pushes the sleeve against the blade.

The '492 patent discloses a safety scalpel in which a spring loaded sheath is actuated to encase the blade when a button is depressed. The knife can be reused many times, and can be withdrawn from the sleeve. Clearly, the knife disclosed by the '492 patent differs from the invention defined by applicants' claims 1 – 6 in that the blade disclosed by the '492 patent is reusable and not firmly supported so as to prevent twisting of the blade during use. On the other hand, the surgical knife required by applicants' claims 1 – 6 is guided by close intimate slots. Blade twisting of the applicants' claimed surgical knife during the single use is virtually eliminated, permitting precision not afforded by the scalpel of the '492 patent. As a result, the surgical knife called for by applicants' claims 1 – 6 is easier to use, more accurate, and safer to operate and dispose of than the '492 patent's

In re application of: Edward Bilenski et al.
Serial No.: 10/822,243
Filed: April 9, 2004
For: SINGLE-USE, SELF-CONTAINED TWIST RESISTANT
SURGICAL KNIFE
Docket No.: 0075-2

scalpel.

These structural and procedural differences provide ample basis for predicated patentability of claims 1 – 6 of applicants' invention over the '492 patent disclosure.

6. U. S. Patent No. 5,417,704 to Wonderley

US Patent 5,417,704 to Wonderley (hereinafter the “704 patent”) discloses a disposable surgical scalpel having a u-shaped plastic safety guard. The blade is carried on one end of the handle and a protective cover is caused to slide over the blade in a protective position, or moved away from the blade to expose the blade. Displacing the guard beyond a wedge permanently locks the knife.

Significantly, the '704 patent discloses a disposable surgical scalpel with a u-shaped guard that can be positioned in one of three positions. The u-shaped guard can be moved rearward to expose the blade, displaced partially forward to temporarily protect the blade, and displaced substantially entirely forward to permanently retract and lock the blade.

Unlike the surgical knife required by applicants' claims 1 – 6, the disposable surgical scalpel disclosed by the '704 patent is clearly not a single-use, self-contained surgical knife. The '704 patent does not utilize a spring mechanism for retracting and protracting the scalpel blade, in fact the blade does not retract or move, instead the guard moves. The u-shaped guard has to be slid over a wedge to achieve a permanently locked condition. This sliding action may require substantial force and close proximity to the blade, increasing the prospect of knife slippage and subsequent injury to the surgeon, hospital staff, or patient.

In re application of: Edward Bilenski et al.
Serial No.: 10/822,243
Filed: April 9, 2004
For: SINGLE-USE, SELF-CONTAINED TWIST RESISTANT
SURGICAL KNIFE
Docket No.: 0075-2

On the other hand, the invention defined by applicants' claims 1 – 6 is conveniently retracted by a single twist, the surgeon's hand does not come in close proximity to the blade and minimal force is required. Particularly, the invention set forth by applicants' claims 1 – 6 provides a 'one-twist' retraction means that is achieved by a knurled member that releases the central spring tension when twisted, thereby retracting the knife into the containment permanently after single use. During use of the applicants' claimed single-use surgery knife the knife blade is both laterally and longitudinally stabilized, for support and prevention of twisting motion during use. Once retracted, the blade remains housed within the containment, preventing subsequent usage by the surgeon and consequent preventing contamination to the patient.

These structural and procedural differences patentably differentiate claims 1 – 6 of the present invention from the '704 patent disclosure.

7. U. S. Patent No. 5,556,409 to Haining

US Patent 5,556,409 to Haining (hereinafter the “409 patent”) discloses a disposable scalpel with a retractable blade. The blade can be positioned in (i) an intermediate retracted position for shipping; (ii) a fully exposed position for use; and (iii) a permanently retracted position for safe disposal. The blade handle has a chamber with projections and the blade carrier has a flexible member. The flexible member engages with the projections to secure the blade in the aforementioned three positions. Pressing a tap with the finger controls the blade motion. The tap is sealed once the blade is retracted.

The '409 patent discloses a disposable surgical scalpel having a blade that has three distinct

In re application of: Edward Bilenski et al.
Serial No.: 10/822,243
Filed: April 9, 2004
For: SINGLE-USE, SELF-CONTAINED TWIST RESISTANT
SURGICAL KNIFE
Docket No.: 0075-2

positions. The blade is moved by pressing on a tap with a finger. This allows sliding of a blade carrier inside the chamber in the handle. Since the carrier has to slide within the chamber over the projections by finger pressure, there is a degree of loose tolerance between the width of the blade carrier and the width of the chamber, allowing twisting motion of the blade. This twisting hinders the precise cutting action necessary by the surgeon. By sliding the blade between the 'use position' and the 'shipping position', the blade can be reused many times. The sliding force needed to lock the blade is not insubstantial and as a result, the surgeon or hospital staff may accidentally be severely cut by the razor sharp blade of the scalpel.

Unlike the knife disclosed in the '409 patent, the surgical knife required by applicants' claims 1 – 6 is a single-use, twist resistant surgical knife that is sterile and ready for use. Applicants' claims 1 – 6 recite a surgical knife having a 'one-twist' turning means that is achieved by a knurled member that releases the central spring tension when twisted, thereby retracting the knife into the containment permanently after single use. Conveniently, the applicants' claimed surgical knife is retracted by a single twist, the surgeon's hand does not come in close proximity to the blade and minimal force is required. Furthermore, the surgical knife recited by applicants' claims 1 – 6 provides for both a lateral stabilization means for supporting a shaft carrying the blade and a stabilization means for preventing twisting of the blade. The invention defined by applicants' claims 1 – 6 delivers precision and accuracy during delicate surgery, and promotes safety by virtually eliminating repeated usage of the knife.

These structural and procedural differences patentably distinguish the invention delineated by applicants' claims 1 – 6 from the '409 patent disclosure.

In re application of: Edward Bilenski et al.
Serial No.: 10/822,243
Filed: April 9, 2004
For: SINGLE-USE, SELF-CONTAINED TWIST RESISTANT
SURGICAL KNIFE
Docket No.: 0075-2

8. U. S. Patent No. 5,741,288 to Rife

US Patent 5,741,288 to Rife (hereinafter the “‘288 patent”) discloses a re-armable single-user safety finger stick device having reset for multiple use by a single patient. A lancet is extended beyond a hole in the body of the device upon actuation to create a small incision to extract a drop of blood for self-test. Upon arming, the lancet carrier is withdrawn, storing energy in a spring in the body of the device. When the lancet is released by pressing a button, the lancet extends outward through a hole in the body over which user’s finger is placed, creating the incision.

The ‘288 patent discloses a multiple use re-armable blood drop extraction device having a lancet carrying member loaded by fixed displacement of a spring. The member is propelled by the spring against the finger to create an incision. Such a device is clearly not intended for a single use. It is not self-contained and has a blade biased into an active, extended condition, not an inactive, retracted condition, by a spring. In contrast, applicants’ claims 1 – 6 disclose a single use, self-contained twist resistant surgical knife and process of making the same.

Unlike the device disclosed in the ‘288 patent, the surgical knife defined by applicants’ claims 1 – 6 is a single-use, twist resistant surgical knife that is sterile and ready for use. The blade of the surgical knife recited by applicants’ claims 1 – 6 is initially found in the extended position so that the blade does not have to be protracted from the containment. When the surgeon finishes using applicants’ claimed knife a knurled ring member is turned by way of a single twist, or “one-twist” turn, triggering retraction of the knife blade into the casing or containment. Multiple use of the knife called for by applicants’ claims 1 – 6 is thereby prevented as the blade is not

In re application of: Edward Bilenski et al.
Serial No.: 10/822,243
Filed: April 9, 2004
For: SINGLE-USE, SELF-CONTAINED TWIST RESISTANT
SURGICAL KNIFE
Docket No.: 0075-2

retractable therefrom. The surgical knife defined by applicants' claims 1 – 6 provides for both a lateral stabilization means supporting a shaft carrying the blade and a stabilization means preventing twisting of the blade. These aforementioned features are not disclosed or suggested by the disclosure of the '288 patent.

These structural and procedural distinctions strongly support patentability of applicants' claims 1 – 6 over the '288 patent disclosure.

9. U. S. Patent No. 5,779,724 to Werner

US Patent 5,779,724 to Werner (hereinafter the “'724 patent”) discloses a retractable surgical knife. The device is similar to a ball pen wherein the blade is pushed out or protracted by pressing a latch mechanism and retracted by again pushing on the latch mechanism.

Significantly, the '724 patent discloses a surgical knife having a blade that is carried in a central carrier, and is prevented from falling out. A new scalpel blade can be attached into the device for re-use of the device. The blade support assembly is pushed forward to expose the blade. A push button is pressed transversely to retract the blade. Clearly, the device disclosed by the '724 patent is not a single use, self-contained surgical knife but is rather has a multiple-use assembly adapted for periodic insertion of new blades.

By way of contrast, the invention recited by applicants' claims 1 – 6 has entirely different structural components. Unlike the device of the '724 patent, the single-use surgery knife required by applicants' claims 1 – 6 comprises a containment means, stabilization means, retraction means, locking means, and a turning means. Specifically, the applicants' claims 1 – 6 require both a lateral

In re application of: Edward Bilenski et al.
Serial No.: 10/822,243
Filed: April 9, 2004
For: SINGLE-USE, SELF-CONTAINED TWIST RESISTANT
SURGICAL KNIFE
Docket No.: 0075-2

stabilization means, by way of at least two shaft support bushings, for supporting a shaft carrying the blade and a stabilization means, having at least a pair of slot faces, for preventing twisting of the blade. The locking means defined by applicants' claims 1 – 6 comprises a rectangular lug and rectangular opening in a knurled ring member so that the knife blade is initially locked in the extended or in 'in-use' position. After a single use of the surgical knife required by applicants' claims 1 – 6 the knurled ring member is turned with "one twist" and the blade is retract permanently into the containment casing.

These structural and procedural distinctions provide ample basis upon which to predicate patentability of applicants' claims 1 – 6 over the '724 patent disclosure.

10. U. S. Patent No. 5,908,432 to Pan

US Patent 5,908,432 to Pan (hereinafter the "'432 patent'") discloses a scalpel with a retractable blade. The blade is retained in a blade holder and is slidable within a channel in the distal section of the handle. This sliding action essentially guards the blade from accidental contact. Pushing a spring-loaded button actuates the retraction function.

The '432 patent discloses an actuated retractable blade in a surgical scalpel wherein the blade slides in a channel in the handle. No disclosure or suggestion is contained by the '432 patent concerning a single-use, self-contained surgical knife. Rather, the knife disclosed by the '432 patent can be reused over and over again.

Unlike the device disclosed in the '432 patent, the surgical knife defined by applicants' claims 1 – 6 is a single-use, twist resistant surgical knife that is sterile and ready for use.

In re application of: Edward Bilenski et al.
Serial No.: 10/822,243
Filed: April 9, 2004
For: SINGLE-USE, SELF-CONTAINED TWIST RESISTANT
SURGICAL KNIFE
Docket No.: 0075-2

The blade of the surgical knife called for by applicants' claims 1 – 6 is initially found in the extended position so that the blade does not have to be protracted from the containment. When the surgeon finishes using the applicants' claimed surgical knife a knurled ring member is turned by way of a single twist, or "one-twist" turn, triggering retraction of the knife blade into the casing or containment. Multiple use of the knife required by applicants' claims 1 – 6 is thereby prevented as the blade is not retractable therefrom. The surgical knife defined by applicants' claims 1 – 6 provides for both a lateral stabilization means for supporting a shaft carrying the blade and a stabilization means for preventing twisting of the blade. These aforementioned features are not disclosed or suggested by the disclosure of the '432 patent.

In light of these structural and procedural differences, the invention presented by applicants' claims 1 – 6 and the '432 patent disclosure are patentably distinct.

11. U. S. Patent No. 6,022,364 to Flumene et al.

US Patent 6,022,364 to Flumene et al. (hereinafter the "364 patent") discloses a disposable surgical safety scalpel. The blade and blade support act as a slider in a shell. They are guided by the shell walls while extending outside into the in-use position, or retracting into an inactive condition within the shell. When the blade is extended, the spring in the handle is stretched to produce tension against a pin. Actuation of the pin releases tension in the spring, retracting the blade into the sheath. Figures 2 and 4, set forth in the '364 patent, indicate the position of the spring in the blade retracted and blade extended conditions.

The '364 patent discloses a surgical blade that is retracted and extended by a spring housed

In re application of: Edward Bilenski et al.
Serial No.: 10/822,243
Filed: April 9, 2004
For: SINGLE-USE, SELF-CONTAINED TWIST RESISTANT
SURGICAL KNIFE
Docket No.: 0075-2

within a handle. No disclosure is contained by the '364 patent concerning a single use self-contained surgical knife. Rather, the blade of the '364 patent device can be retracted and then brought back into the operating position numerous times. Blade rigidity is maintained by the large area over which the blade holder slides against the sides of the shell. A large clearance must thus be provided to allow for extension and retraction of the blade. Due to the clearance required by the '364 patent device, the blade is not held completely rigid. Consequently, it may be difficult for the surgeon to produce precise incisions when using the scalpel disclosed by the '364 patent.

On the other hand, the invention called for by applicants' claims 1 – 6 is conveniently retracted by a single twist, the surgeon's hand does not come in close proximity to the blade and minimal force is required. Particularly, the invention recited by applicants' claims 1 – 6 provides a 'one-twist' retraction means that is achieved by a knurled member that releases the central spring tension when twisted, thereby retracting the knife into the containment permanently after single use. During use of the applicants' claimed single-use surgery knife the knife blade is both laterally and longitudinally stabilized, for support and prevention of twisting motion during use by having a plurality of slots to provide blade support and stability. Once retracted, the blade remains housed within the containment, preventing subsequent usage by the surgeon and consequent preventing contamination to the patient. The invention recited by applicants' claims 1 – 6 allows for safe, rapid, and effortless retraction of the knife blade, virtually eliminating undesirable subsequent usage of the knife. This structural component combination makes the applicants' claimed surgical knife easier and safer to use and more accurate and reliable in operation than the

Margaret:

Claims never disclose, set forth, describe, provide, illustrate or reveal.

Claimed subject matter is defined, recited, called for, required and delineated by the claims.

On the other hand.

Documents disclose, describe, provide, illustrate and reveal.

Neither claims nor documents set forth.

Comments can be set forth in a letter. Information (for example tabular data) can also be set forth or listed below.

Ernie Buff

In re application of: Edward Bilenski et al.
Serial No.: 10/822,243
Filed: April 9, 2004
For: SINGLE-USE, SELF-CONTAINED TWIST RESISTANT
SURGICAL KNIFE
Docket No.: 0075-2

'364 patent's scalpel. The '364 patent disclosure thus differs from the invention delineated by claims 1 – 6 in terms of form, functionality, and design.

When compared to any device constructed in light of the '364 patent disclosure, the presence of substantial structural and functional differences make the invention recited by claims 1 – 6 patentably distinct.

Respectfully submitted,
Edward Bilenski et al.



By _____
Ernest D. Buff
(Their Attorney)
Reg. No. 25,833
(908) 201-0220

0075-2-PMSDDR1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Edward Bilenski et al. Group Art Unit: 3731
Serial No.: 10/822,243 Examiner: N/A
Filed: April 9, 2004
For: **"SINGLE-USE, SELF-CONTAINED TWIST RESISTANT
SURGICAL KNIFE"**
Matter No.: 0075-2

231 Somerville Road
Bedminster, NJ 07921
August 19, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Certificate of Mailing by First Class Mail

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on August 19, 2004.


Signature

Ernest D. Buff
Attorney of Record

August 19, 2004
(Date)